

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Offic**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/402,737 10/08/99 NEUSER

D BAYER10197

EXAMINER

HM12/0919  
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ART UNIT	PAPER NUMBER
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1616

DATE MAILED:

09/19/00 9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/402,737	NEUSER ET AL.
Examiner	Art Unit	
Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a) All b) Some \* c) None of the CERTIFIED copies of the priority documents have been:
    1. received.
    2. received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
    3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	20) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

Claims 1-4 are pending in this application.

### ***Action Summary***

1. The rejection of record of claim 2 made under 35 U.S.C. 102(e) over Bourke et al. is hereby expressly withdrawn.
2. Applicant's arguments filed August 11, 2000 have been fully considered but they are not persuasive.
3. The rejection of claims 1, 3 and 4 of record made under 35 U.S.C. 102(e) over Bourke et al. is being maintained for the reason stated.

### ***Response to Arguments***

4. Applicants argue that the examiner failed to explain how Bourke et al. single active agent satisfies both elements A and B according to the claims and the specific limitations of dependent claims 2-4. The prior art teaches the composition containing the analgesic Naproxen having both locally and systemically acting properties. Applicant does not claim that the analgesics are different. The prior art states that the first portion has a drug maintenance function in blood levels and the second portion has a relatively immediate therapeutic response. Relatively immediate therapeutic response to the examiner means that it has rapid onset of action. To answer the argument about claim 3, col. 3, lines 3-7 states "The applicants have found in the case of the above formulations of the present invention, that therapeutically effective blood levels can be maintained substantially over 24 hours with peak plasma levels occurring between 2 to

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16 hours, preferably between 4 to 10 hours." This implies that the formulation of the prior art satisfies the duration of action of the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourke et al. (USPN 5,637,320).

Bourke et al. ('320) teaches a formulation for oral administration in a multiparticle form, where the first portion is designed to release the drug at a rate as to maintain therapeutically effective blood levels (i.e. sustained release) and a second portion is formulated so as to release the drug promptly following administration to obtain a relatively immediate therapeutic response (i.e. rapid release) (col. 1, lines 60-67 and col. 2, lines 1-2). The reference teaches the drug as an analgesic i.e. naproxen (col. 1, lines 17-19). The reference teaches formulations of the invention maintaining a therapeutic effect over a 24hr period with peak levels between 2-16 hours (col. 3, lines 3-7). The reference teaches the formulations further containing lubricants and polymeric materials (col. 3, lines 23, 28-30). The reference does not teach the duration of action for the relatively immediate response component.

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However, it would have been obvious to one of ordinary skill in the art to recognize that relatively immediate response time are usually within minutes of absorption into the blood stream.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

KMG



Shelley Dodson  
Primary Examiner  
Art Unit 1616